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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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09/486,266 05/03/00 HILLE

T FLA-0035

EXAMINER

HM22/0531

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ART UNIT

PAPER NUMBER

1615

7

DATE MAILED:

05/31/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/486,266

Applicant(s)

HILLE ET AL.

Examiner

Isis Ghali

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 May 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicants' preliminary amendment and I.D.S., both filed 5/3/2000.

Note that only one sheet of Form PTO 1449 was received.

Specification

1. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 22-57 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The elasticity was not discussed in applicants' disclosure sufficiently as far as its definition or how it can be measured, in such a way to enable one skilled in the art to practice the invention and deliver a backing with the claimed degree of elasticity. The "redetachable protective layer" as well as "warp thread" and "weft thread", are not described in a sufficient

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way to enable one skilled in the art to practice the invention. Regarding claim 38, “obtainable by the reaction of starting material”, is enabling as there is no disclosure of the nature of the reaction in order to obtain the claimed material.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 22-57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 22-57, the expression “elasticity of at least 20%”, it is unclear as percentage of what?.

Regarding claims 32 and 33, it is unclear what the applicants meant by “micobially nondegradable”?.

Regarding claim 38, the claim contains improper Markush format. Proper Markush format to be followed in the claim should have the expression “selected from the group consisting of”, and only the last two members of the Markush group are separated by the connector operator “and” OR “or”.

Regarding claim 50, what is “areal proportion”?.

Regarding claims 51-53, what are the “wrap thread” and “weft thread”?.

The claims are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 22-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,240,711 ('711) by itself or in combination with US 5,246,705 ('705) or US 4,466,953 ('953).

US '711 disclosed a transdermal therapeutic system for controlled release of buprenorphine comprising a backing, pressure sensitive adhesive reservoir and a removable protective layer. The backing is impermeable to the active ingredients and flexible (elastic) and may be coated by polymeric substrate. The reservoir layer consisting preferably from polyvinylpyrrolidone. The transdermal system is produced by spreading the active substance containing solution on the backing and punching after drying. See abstract; col.3, lines 9-19, 51-52; col.4, line 67 till col.5, line 5.

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The reference does not teach percentage of elasticity or the material of the backing , not the water vapor transmission of the backing.

No superior and unexpected results were established showing the criticality of the claimed elasticity or in particular material used. No criticality was shown in the claimed water vapor transmission, or in the ranges of wrap thread and weft thread. It is within the skill in the art to have differentiated marking elements.

US '705 disclosing a transdermal drug delivery system comprising elastomeric backing made of polyethylene or polypropylene having a moisture vapor transmission of about 0.1 to 20 g/m²/hr. The transdermal system used to deliver analgesics and hormones in an adhesive reservoir layer. See abstract; col.2, lines 6-15; col.3, lines 27-43; col.4, lines 15-41.

US '953 is teaching a polymeric diffusion matrix made of polyvinylpyrrolidone containing analgesics and hormones; a backing in the form of elastic band made of polyethylene terephthalate; and a release liner. See col.2, lines 13-25; col.3, lines 56-61; col.7, lines 1-23, 48-50, 58, 62.

Accordingly, it would have been obvious to one having ordinary skill in the art at the time of the invention to deliver transdermal therapeutic system comprising adhesive reservoir layer containing the active ingredient; a release liner; and a backing, and adjusting the elasticity of the backing to obtain a certain elasticity with reasonable expectation of success of delivering a comfortable patch.

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 5,846,558 disclosed ionically conductive adhesive used in medical devices.


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10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (703) 305-4048. The examiner can normally be reached on Monday through Thursday from 7:00 AM to 5:30 PM, Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Isis Ghali
Examiner
Art Unit 1615


THURMAN K. PAGE
SUPERVISOR, PATENT EXAMINER
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